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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,739	11/08/2001	James C. Copeland	OXR 2 0025	4971
7590 07/28/2004				
FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP 7th Floor 1100 Superior Avenue Cleveland, OH 44114-2516			EXAMINER PORTNER, VIRGINIA ALLEN	
			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/007,739

Applicant(s)

COPELAND ET AL

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-35 are pending.

#### ***Rejections Withdrawn***

1. The rejections of claims 1-3, 9,26,28-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been obviated through amendment of the claims.

#### ***Rejections Maintained***

2. The rejections of claims 6 and 8 (paragraph d) under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have not been obviated as the claims have not been amended to address the clarity issues raised of record.

3. Claims 1,3-5, 7-9 rejected under 35 U.S.C. 102(b) as being anticipated by Merad et al (1992) is maintained for reasons of record in paper number 6, paragraph 6.

4. Claims 1-2,4-5 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (1984), is maintained for reasons of record in paper number 6, paragraph 7.

5. Claims 10-12,15-17,20, 22 rejected under 35 U.S.C. 102(b) as being anticipated by Blondin et al (US Pat. 4,808,517) for reasons of record in paper number 6, paragraph 8.

6. Claim 27 rejected under 35 U.S.C. 102(b) as being anticipated by Tillonen et al for reasons of record in paper number 6, paragraph 9.

7. Claims 1-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) for reasons of record in paper number 6, # 11.

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8. Claims 28-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) for reasons of record in paper number 6,#12.

***Response to Arguments***

9. The rejections of claims 6 and 8 (paragraph d) under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is traversed on the grounds that the claims have been amended to address the examiner's concerns thus obviating the rejections made of record.

10. It is the position of the examiner that claim 6 was not amended to recite the phrase – further comprises--; a claim can not further limit a reagent that is not previously provided. With respect to claim 8, the 112 second paragraph rejection has been partially obviated through amendment of the claim, but paragraph d. is still unclear as only a single “a medium composition” is inoculated, and paragraph d. compares growth in the medium with partial growth with azide thus defining two growth medium, but only a single medium was inoculated. Claim 8 paragraph d, is still unclear.

11. The rejection of claims 1,3-5, 7-9 under 35 U.S.C. 102(b) as being anticipated by Merad et al (1992) is traversed on the grounds that the growth medium with 0.1% sodium azide did not result in the “selective enhancement of the growth of the anaerobes (and not facultative microbes).

12. It is the position of the examiner that the instantly claimed composition comprises a medium that comprises a nutrient medium and an azide salt, wherein the concentration of the

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azide salt is about 0.1 mg/ml to 1.0 mg/ml (instant claim 3). The azide concentration of Merad et al is:

\* (Conc. Recited in instant claim 3)  $1 \text{ mg/ml} = 100 \text{ mg/100ml} = 0.1 \text{ g/100 ml} = 0.1\%$  sodium azide (Conc.

Used and taught to be most effective by Merad et al, see English abstract last line and page 165,

col. 4, "0.1%" azide) . \* A nutrient medium with a concentration of 0.1% sodium azide uses

azide at the upper limit of the azide concentration recited in instant claim 3, therefore,

Applicant's arguments asserting distinctiveness based upon the recited functional limitations is

not convincing based upon the structural components of Merad et al and what is instantly

claimed are identical.

13. The rejection of claims 1-2,4-5 and 9 under 35 U.S.C. 102(b) as being anticipated by Jones et al (1984), is traversed on the grounds that "In no way does this article disclose or suggest that anaerobe microbes would also exhibit tolerance to azides and/or that the use of azides would result in the selective growth of anaerobic microbes contained in a mixed sample also containing facultative microbes."

14. It is the position of the examiner that:

a. Jones et al disclose a anaerobic medium composition that comprises:

i. nutrient broth medium

ii. a salt of an azide (see page 99, Table 2, top of page; page 97, ledger for Figure 1, "sodium azide"), the concentration of which is about 0.1 mg/ml.

The term "*about*" is being read to include values above and below 0.1 mg/ml and the

concentration of azide of Jones et al was 0.064 mg/ml which is about 0.1 mg/ml. Applicant's

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recited range for azide reads on the concentrations used by Jones et al in the disclosed nutrient broth. The concentration was expressed as

1mM azide = 0.064 mg/ml which, when rounded up, is **about** 0.1 mg/ml

[64 grams/mole Sodium Azide ( $\text{Na N}_3$ ); 64 g/1000ml = 1M; 0.064 g/ml = 1M; 0.000064 g/ml = 1mM; 0.064 mg/ml = 1mM]

Applicant has not structurally distinguished the medium claimed from the medium of the prior art that discloses the same or equivalent composition that comprises a nutrient medium together with **about** 0.1 mg/ml sodium azide. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

15. The rejection of claims 10-12, 15-17, 20, 22 under 35 U.S.C. 102(b) as being anticipated by Blondin et al (US Pat. 4,808,517) is traversed on the ground that the medium comprises a salt of azide and has an intended use for growth of anaerobic microorganisms.

16. It is the position of the examiner that the claims to which Blondin et al has been applied do not recite, nor structurally require the only electron transport inhibitor to be a "salt of azide", and the recited intended use of the claimed composition does not structurally distinguish the claimed combination of components, because the recited functional characteristics, and the specifically recited structural components are disclosed in a composition by Blondin et al. The claim limitations of claim 18 were not rejected by the application of Blondin et al which only recites the term "azide". Claim 17 recites the term "cyanide" which is present in the composition of Blondin et al. While the specification can be used to provide definitive support, the claims

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are not read in a vacuum. Rather, the claim must be definite and complete in and of itself.

Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. The rejection is maintained for reasons of record; Applicant's traversal is not commensurate in scope with the instantly claimed invention. The claims to which Blondin et al was applied encompass the utilization of a substance that inhibits electron transport, specifically electron transport (cyanide and antimycin) , and therefore meets the recited functional claim limitations.

17. The rejection of claim 27 under 35 U.S.C. 102(b) as being anticipated by Tillonen et al is traversed on the grounds that the composition of prior art "has nothing to do with the present invention".

18. It is the position of the examiner that while the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. What is now claimed is a composition, and not a method. The instantly claimed composition has not been distinguished over the applied prior art through the recitation of an intended use.

19. Claims 1-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) and Claims 28-35 rejected under 35 U.S.C. 103(a)

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as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) were not addressed by Applicant and therefore maintained for reasons of record..

*New Claim Limitations/New Grounds of Rejection*

*Claim Rejections - 35 USC § 112*

20. Claim 29 recites the limitation "medium composition containing the mixed sample" and "medium composition" in paragraphs b. and c, respectively. There is insufficient antecedent basis for this limitation in the claim. Claim 29 has been amended into independent form and no longer depends from claim 28 which provided for antecedent basis for the phrase "medium composition". The medium composition of paragraph b. appears to be different from the medium composition of paragraph c, both of which do not evidence support and antecedent basis in the preamble or paragraph a. of the claim.

*Conclusion*

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,




however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat. 6485947 (respiration inhibitors are disclosed to include antimycin, cyanide and azide (detail description paragraph 51); 5871952 (metronidazole and 1mM sodium azide was used to isolated anaerobically treated cells; detail description paragraph 11) ;4882280 (anaerobic agar culture medium with 0.02% sodium azide (detailed description paragraph 62) ; 4528199 (discloses dextrose azide agar, detailed description paragraphs 31,38 and Table 4).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

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July 21, 2004